

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation, *et al.*

Defendants.

Civil Action No. 04-12457 PBS

TRIAL BRIEF OF DEFENDANTS ARTHREX, INC. AND PEARSALLS LTD.

Dated: July 24, 2007

Charles W. Saber
Stephen A. Soffen
Salvatore P. Tamburo
DICKSTEIN SHAPIRO LLP
1825 Eye Street, N.W.
Washington, D.C. 20006-5403
Telephone: (202) 420-3116
Facsimile: (202) 420-2201

Christopher Weld, Jr. (BBO # 522230)
Raymond P. Ausrotas (BBO # 640315)
TODD & WELD LLP
28 State Street, 31st Floor
Boston, MA 02109
Telephone: (617) 720-2626
Facsimile: (617) 227-5777

Counsel for Defendants
Arthrex, Inc. and Pearsalls Ltd.

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I. INTRODUCTION

Pursuant to the Court's June 19, 2007 Pretrial Order, defendants Arthrex, Inc. ("Arthrex") and Pearsalls, Ltd. ("Pearsalls") (together, "defendants") submit this Trial Brief in connection with the upcoming trial scheduled to commence on August 6, 2007. The scheduled trial will only consider the issues of whether defendants infringe the asserted claims of U.S. Patent No. 5,314,446 ("the '446 patent").¹ As we show below, and will demonstrate at trial, the evidence overwhelmingly shows that there is no infringement.

While evidence on several issues relating to infringement will be introduced at trial, the principal issue is whether the coating added to Arthrex's FiberWire suture materially affects the basic and novel characteristics of the claimed invention of the '446 patent. This issue is paramount because the claims of the '446 patent all contain the transitional phrase "consisting essentially of." In such circumstances, there is no infringement, where, as here, the accused product contains an ingredient not recited in the claims and where that ingredient materially affects the basic and novel characteristics of the claimed invention.

It is undisputed that FiberWire suture contains a coating and that coating is not recited in the claims of the '446 patent. It is also undisputed that coating materially improves the handleability, and especially knot tie down performance of suture. Patent after patent -- most of them owned by DePuy Mitek's sister company, Ethicon, or DePuy Mitek's own expert in this case -- make this universally-known assertion.² Every *DePuy Mitek and Ethicon* witness who testified on this subject -- *all six of them* -- likewise agreed. As a result, it comes as no surprise

¹ Defendants also believe that the claims of the '446 patent are invalid and unenforceable. Those issues, however, are not the subject of the upcoming trial, but rather, are preserved for later, if necessary.

² Defendants note that they are not filing any exhibits with their Trial Brief. This Trial Brief refers to evidence already submitted by defendants in prior filings with the Court, including their summary judgment papers. Thus, the Court already has the exhibits relied upon in this Trial Brief.

that Arthrex repeatedly tells the world that coating is added to FiberWire to improve its handleability.

On this basis alone, defendants should prevail. But there is much more. Both before institution of this litigation and after being sued, defendants commissioned a series of tests which confirmed the universally-known facts that that Arthrex's coating materially affects the handleability and pliability of the FiberWire suture. In addition, defendants will present irrefutable evidence about the reason that coating is added to FiberWire as well as how it is done. At the end of the day, there is nothing that plaintiff DePuy Mitek can do to change these long and universally-known facts. At the end of the day, there is no infringement.

II. THE ACCUSED FIBERWIRE SUTURE DOES NOT INFRINGE THE ASSERTED CLAIMS OF THE '446 PATENT

A. The Addition of Coating to FiberWire Avoids Infringement Because Coating Materially Affects the Basic and Novel Characteristics of the '446 Patent

It is undisputed that FiberWire includes a coating, and that coating is not a listed item in the asserted claims. The evidence will definitively show that the FiberWire coating materially affects the basic and novel characteristics of the claimed invention by providing the known and important advantages to suture handleability and pliability.

The first step is to define the basic and novel characteristics of the claims of the '446 patent. The Court has already construed those basic and novel characteristics to be: (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture.³

³ As the Court made clear in its claim construction Order, it is the handleability and pliability *of the suture* that is improved by braiding together two dissimilar yarns. For example, in supporting its claim construction, the Court noted "of significance, the specification states: in

The next step is to determine whether coating materially affects those basic and novel characteristics. An effect on the basic and novel characteristics of the claimed invention is “material” if the effect is of importance or of consequence to those of ordinary skill in the art. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). As we show below, the evidence is overwhelming that coating’s affect on suture pliability and handleability, and especially knot tie-down, are of importance or of consequence to those of ordinary skill in the art.

The evidence in the case overwhelmingly shows that the reason why multifilament sutures are coated is to improve the pliability and handleability aspects of the suture, particularly the knot tie down characteristics.⁴ One need only look at the *uniform and overwhelming* evidence from DePuy Mitek itself, and from Ethicon, DePuy Mitek’s sister company and the leading suture manufacturer in the world, to understand that this fact is so well-known in the suture art that it hardly bears citation.

(1) Ethicon patent after Ethicon patent, including patents of Alistair Hunter, one of the inventors of the ‘446 patent, explain the importance of coating multifilament sutures. One such patent explains that “a multifilament suture typically requires a surface coating to improve the tactile smoothness, pliability and tiedown performance of the suture”); still another states that “multifilament suture [*sic*] typically require a surface coating to improve the pliability and knotting characteristics of the suture.”

(2) A patent of Dr. Matthew Hermes, one of DePuy Mitek’s experts in this case, makes the same assertion. According to the Hermes patent, “[i]t has therefore become a

view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties.”

⁴ As Ethicon’s own Wound Closure Manual explains, knot tie down is the ease by which a knot slides down the suture.

common practice to coat sutures, particularly those of the multifilament variety, with compositions which improve their knot tie-down performance and perhaps one or more other properties of the sutures as well.”

(3) Ethicon’s Wound Manual makes the same point. It states: “Multifilament sutures may also be coated to help them pass relatively smoothly through tissue and enhance handling characteristics.”

(4) Every DePuy Mitek and Ethicon fact witness who testified on the subject of why sutures are coated agreed. Whether testifying about the development of the suture for the ‘446 patent, Ethicon’s and DePuy Mitek’s development of Orthocord, or testifying about what is known to be important to those involved in suture, the testimony was exactly the same:

(a) Dr. Mark Steckel, a named inventor on the ‘446 patent, testified as follows:

Q: [The ‘446 patent] says, “For example, multifilament sutures almost universally possess a surface coating to improve handling properties.” Do you see that?

A: Yes.

Q: What’s your understanding of what handling properties are being referred to in that sentence?

A: My understanding, because the surface coating would be for knot handling, knot tie-down handling properties.

Q: How about how well the knot slides, is that one of the things that --

A: Oh yeah, that’s part of knot tie-down.

Q: Why don’t you explain to me what is part of knot tie-down.

A: Okay. Yeah. I mean knot tie-down refers to the properties of a suture during the tying process, which would include the force, smoothness, roughness when one arm of the suture is being pulled against the second arm of the suture.

(b) Dennis Jamilkowski, one of the originally-listed inventors of the ‘446 patent, and plaintiff’s Rule 30(b)(6) witness, testified as follows:

A: Because sutures are frequently coated. In particular, braids are very often coated.

Q: Why is that?

A: Because a braid surface is not very smooth, generally, and consequently, tends to chatter much more than would a monofilament upon knot tie-down. So what the industry has done is that these suture materials that are multifilament in nature, that is, braids, would generally be coated. Not always, but generally.

(c) Shelby Cook Cornbluth, Project Leader on development of Orthocord suture, and also a Rule 30(b)(6) witness for plaintiff, testified as follows:

Q: Why is there coating on [Orthocord]?

A: To help with knot sliding.

Q: What do you mean when you say "To help with knot sliding"?

A: To help the knot slide down into the joint so that it cinches tightly. It – you want the knot to travel down the suture.

Q: Okay.

A: And it helps with that traveling down the suture.

(d) Gary McAllister, DePuy Mitek's Director of R&D for Orthocord suture, testified as follows:

Q: Why is there a coating on [Orthocord]?

A: It makes the handling much better, is my understanding that that's why coatings are put on there. It'll tie better. It'll slide better. They call it the hand. It improves the hand of the suture.

(e) Ilya Koyfman, Ethicon's technical leader in charge of developing Orthocord suture, testified as follows:

Q: I want to ask you a little bit about the -- what comes under the heading "braiding through coating" et cetera. Particularly, the last paragraph on the page. The sentence that says, "Coating selection depends on maintaining a fine balance between suture tie-down and knot security.

A: Um-hm.

Q: What did you mean by that sentence?

A: The prime reason for applying coating is to have a good tie-down, good tie-down and tissue passage and so forth. When you apply coating you might affect other properties. So that's what I meant, you have to have a balance.

(5) Ethicon and DePuy Mitek documents clearly demonstrate Ethicon's and DePuy Mitek's understanding that coating affects handleability when developing their Orthocord product (which competes directly with FiberWire) and other suture products. For example,

DePuy Mitek touts that Orthocord is coated “for improved slide ability and enhanced knot tying characteristics (*e.g.* knot slide).”

(6) Articles in the field concur that “synthetic sutures have been coated to decrease their coefficient of friction and improve their handling characteristics.”

In light of this overwhelming evidence, it comes as no surprise that Arthrex’s documents, in a mirror image of DePuy Mitek’s and Ethicon’s documents and testimony, confirm that coating is added to improve handling characteristics. For example, Arthrex’s Directions for Use of FiberWire explains that “[t]he coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue.” Likewise, defendants’ witnesses will testify that coating was added to FiberWire precisely for these known reasons. As a result, Arthrex could sell a suture that its customers wanted and could easily use.

In addition, defendants performed internal tests as well as commissioning a well-known testing expert (Dr. Norman Gitis of the Center for Tribology, who performed a series of tests to show objective proof of the effect of coating on FiberWire. Not surprisingly, that testing evidence confirms the universally-known truth that coating has a material effect on suture handleability and pliability. Finally, defendants will present the testimony of its suture expert, Dr. Mukherjee, a bioengineering professor who teaches doctors about suture properties and who spent years in industry formulating and making sutures, who will explain that FiberWire’s coating has a materially effects on the suture’s pliability and handleability.

DePuy Mitek has never disputed defendants’ overwhelming evidence that coating materially affects handleability features of sutures. Unable to dispute the indisputable, DePuy Mitek tries to change the question and essentially takes the position that FiberWire, somehow, is the only suture ever created where coating does not affect handleability characteristics. It, however, never had any real evidence to support such a notion.

DePuy Mitek apparently will rely on the testimony of Dr. Brookstein to try to create the illusion that FiberWire's coating does not materially affect the basic and novel characteristics of the claimed invention. Even if Dr. Brookstein were qualified to testify on the subject of suture coating -- he worked on only one suture project in his professional life and he could not remember if it involved issues of coating, and he was unable to confirm or deny the universal teachings about the effects of coating shown in the numerous patents and publications placed before him⁵ -- he never refutes *any* of the evidence presented by defendants regarding coatings well-known effects on suture handleability.

Apparently, Dr. Brookstein will contend that FiberWire's two different yarns -- UHMWPE and PET -- contribute different properties to the braided suture and that the contribution of different properties is present both before and after coating is added. Therefore, coating does not materially affect the basic and novel characteristics of the claimed invention.

Stated another way, Dr. Brookstein asserted in his expert report that coating does not affect the basic and novel characteristics of the claimed invention because "the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided." When asked what this means, Dr. Brookstein replied at his deposition that coating could only affect the basic and novel characteristics if "the coating in some *miraculous* way made those materials not yarns anymore" or "all of a sudden you had a set from A, a set from B and now it was some *magical structure* that wasn't yarns, it wasn't two sets, they were all the same, that would be a transformation." Just to state the proposition shows its absurdity. In DePuy Mitek's and Dr. Brookstein's world, only "magic" and "miracles" can cause an added material to affect the basic and novel characteristics of an invention. That plainly is wrong. It is also contradicted by the law. If Dr.

⁵ Defendants have filed an *in limine* motion against Dr. Brookstein because he is unqualified to testify about coating issues as it relates to suture properties.

Brookstein's theory were accepted, it would mean that the coating would have to eliminate other claim limitations (for example, the UHMWPE or the PET would not be yarns anymore). The Federal Circuit flatly rejected that test in *PPG Indus. v. Guardian Indus. Corp.*, *supra*, 156 F.3d at 1354.⁶

Dr. Brookstein's opinion that the amount of coating on FiberWire is "small" means nothing. "Small" is a relative term and Dr. Brookstein did not compare it to anything. Moreover, the evidence will show that, in the proper context, it is not a small amount.⁷

For all these reasons, and others to be presented at trial, Arthrex's FiberWire suture does not infringe the asserted claims of the '446 patent.

B. Defendants other infringement defenses

Defendants also assert that the adhesive applied to the ends of the FiberWire suture ("tipping") also materially affects the basic and novel characteristics of the claimed invention. Like coating, adhesive is not an ingredient identified in the claim. Moreover, the tipping materially affects the pliability and handleability of the FiberWire suture. It materially affects

⁶ Long after discovery closed, DePuy Mitek presented a new argument that the FiberWire coating has no material effect because the coating benefits are minimal compared to the benefits obtained from braiding together the UHMWPE and PET. Defendants' *in limine* motion seeks to prevent DePuy Mitek from making this new argument. In any event, DePuy Mitek has no evidence to support this argument and its reliance on Dr. Brookstein fails because he never rendered any opinions on this new contention.

⁷ DePuy Mitek's attempted reliance on its assertion that the patent states that if desired, the surface of the braid can be coated to further improve handleability and knot tie-down is both legally and factually wrong. Legally, it is irrelevant because a product can materially affect the basic and novel characteristics of the claimed invention even though the patent discloses that such ingredients can be used. *See, e.g., Kim v. Conagra Foods, Inc.*, 465 F.3d 1312, 1319-20 (Fed. Cir. 2006); *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1242 (Fed. Cir. 2001). Factually, the patent disclosure does not support DePuy Mitek because the patent teaches that it is best to eliminate and avoid coating to save money and avoid braid stiffening issues.

DePuy Mitek's reliance on the deposition testimony of defendants' expert Dr. Burks hardly carries weight. After all, Dr. Burks correctly identified the coated and uncoated suture correctly *each and every time* he tested it, both for his expert report and at his deposition.

suture pliability because the adhesive stiffens the suture and prevents the fibers from moving.

The adhesive also improves the suture's handleability by facilitating attachment to instruments.

Defendants also assert a defense based on the reverse doctrine of equivalents. Under this doctrine, there is no infringement where an accused product is so far changed in principle from a patented article, but nevertheless falls within the literal words of the claim. *See, e.g., Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.*, 279 F.3d 1357, 1368 (Fed. Cir. 2002).

The specification of the '446 patent describes that the first fiber-forming materials are added to improve suture handleability and pliability and that such materials are too weak for most suture applications. The specification goes on to explain that the second fiber-forming materials are added for increased strength. The two fibers in FiberWire act in the *precise opposite* manner. UHMWPE (the alleged first fiber-forming material) is added for strength and PET (the alleged second fiber-forming material) is added to improve handleability.

C. Pearsalls does not contribute to the alleged infringement

DePuy Mitek does not allege that Pearsalls directly infringes the asserted claims of the '446 patent. They cannot because Pearsalls does not make, use, sell, offer to sell or import "surgical sutures." Instead, Pearsalls manufactures the braids that are used by others to make the FiberWire suture. As a result, DePuy Mitek's theory is that Pearsalls contributes to the infringement of the claims.

To establish contributory infringement, Mitek must prove that

- (1) Pearsalls sold or supplied;
- (2) a material component of the patented invention that is not a staple article of commerce capable of substantial non-infringing use; and
- (3) with knowledge that the component was especially made or adapted for use in an infringing product.

35 U.S.C. § 271 (f)(2). DePuy Mitek cannot meet its burden because braids made of the same components used in FiberWire – UHMWPE and PET – can and are used in other, non-infringing products.

III. ISSUES TO BE DECIDED BY THE COURT BEFORE TRIAL

Defendants submit that the Court consider a ruling on the following issues before trial:

A. *In limine* motions

Defendants have submitted the following *in limine* motions:

1) Defendants Arthrex, Inc.’s and Pearsalls, Ltd.’s Motion in Limine To Preclude Dr. Brookstein from Testifying as an Expert at Trial Regarding the Effect of Coating on FiberWire’s Properties or Performance; and

2) Defendants Arthrex, Inc.’s and Pearsalls, Ltd.’s Motion in Limine To Preclude DePuy Mitek from Arguing at Trial that Coating’s Effect on FiberWire is Minimal Compared to the Effect of Combining Two Different Materials.

Defendants request that the Court rule on these motions before trial.

B. Jury instructions

The parties have submitted joint proposed jury instructions. The parties agree on many of the instructions. There are some where the parties disagree. Some of those disagreements may be resolved based on the Court’s pretrial rulings. Others involve relatively minor differences which, defendants believe, are better resolved during the trial if the parties cannot reach agreement.

One area that the Court may wish to consider is the substantive instructions on “consisting essentially of.” Plaintiff’s proposal is numbered ¶ 2.3.5. Defendants’ proposal is numbered ¶¶ 2.3.4 and 2.3.6. Plaintiff proposes a bare bones instruction that does little more than provide the basics of the law on “consisting essentially of” and gives the jury no guidance

on how to apply the facts to this complicated and unusual area of law. Defendants' proposal, on the other hand, tries to provide the jury with better guidance on how to apply the law in this area by providing further instructions outlining the various factors considered by the Federal Circuit in applying the facts to "consisting essentially of" patent claims.

Defendants do not object if the Court believes that this issue is better resolved at a later point in the proceedings.

C. Stipulations of fact

The parties have submitted a joint list of stipulated facts in the Joint Pretrial Memorandum. Defendants submit that plaintiff has unreasonably refused to stipulate to the following fact and requests that the Court order this fact be stipulated to:

1. Defendants' Proposed Stipulated Fact #1:

The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 286, was manufactured for Arthrex as part of a special batch of coated and uncoated samples that were made according to development trial number DT PS05T2 (Hallett 1/11/2006 Dep. at 38:17-39:6; 39:12-18; 40:2-9, 12-17; 41:5-11; DMI Ex. 279; Hallett 1/12/2006 Dep. at 250:4-251:3).

Defendants do not understand how DePuy Mitek cannot agree to this fact. This fact is taken from direct questions asked of Mr. Hallett by DePuy Mitek's counsel at his January 12, 2006 deposition, to which he answered, "That's correct."

D. Witness list

Defendants' have objected to Dr. Mathew Hermes, one of plaintiff's expert, to the extent that he plans to testify beyond the scope of the opinions expressed in paragraphs 57-61 of his rebuttal report dated April 13, 2006. Those paragraphs, where he discusses a pretrial test of coated vs. uncoated FiberWire suture conducted by Arthrex, is the only place in his expert report where he discussed any of the infringement issues involved in this trial.

Plaintiff has indicated that Dr. Hermes may also provide testimony about the teachings of the '446 patent. Any discussion in Dr. Hermes reports about the teachings of the '446 patent were in connection with his view of the proper claim interpretation of the term "PE" or in connection with invalidity and/or unenforceability issues. None of these issues are being litigated in this trial.

Plaintiff has also indicated that Dr. Hermes may testify about materials in Dr. Steckel's (one of the named inventors on the '446 patent) development notebooks in the event Dr. Steckel does not testify. Any discussion in Dr. Hermes reports about those notebooks, however, relate only to the PE claim construction issue or invalidity and/or unenforceability, issues that are not currently before the Court.

Plaintiff should also be precluded from eliciting testimony from Dr. Hermes on any other unnamed subject except as it relates to paragraphs 57-61 of his rebuttal report.

E. Exhibit list

The parties have exchanged Exhibit Lists and their respective objections. Many of those objections may be resolved or substantially narrowed based upon pretrial rulings of the Court. In addition, it may be unnecessary to resolve many of the objections because defendants believe that both parties may choose not to seek to admit many of the identified exhibits or the objecting party may not assert its objection depending upon the context in which an exhibit is offered. Thus, defendants believe that the objections to the exhibits should be reserved and, where necessary, decided during trial.

F. Deposition designations

The parties have exchanged proposed deposition designations, counter designations, counter-counter designations and objections thereto. Defendants submit that it is premature for the Court to resolve these objections. Various pretrial rulings may affect those objections and

the testimony that each party may ultimately offer may be truncated. Accordingly, defendants submit that the parties should continue to seek agreement on proper designations and only involve the Court at a later time as may become necessary.

Dated: July 24, 2007

Respectfully submitted,

By: /s/Charles W. Saber

Charles W. Saber

Stephen A. Soffen

Salvatore P. Tamburo

DICKSTEIN SHAPIRO LLP

1825 Eye Street, N.W.

Washington, D.C. 20006-5403

Telephone: (202) 420-3116

Facsimile: (202) 420-2201

Christopher Weld, Jr. (BBO # 522230)

Raymond P. Ausrotas (BBO # 640315)

TODD & WELD LLP

28 State Street, 31st Floor

Boston, MA 02109

Telephone: (617) 720-2626

Facsimile: (617) 227-5777

Counsel for Defendants

Arthrex, Inc. and Pearsalls Ltd.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing TRIAL BRIEF OF DEFENDANTS ARTHREX, INC. AND PEARSALLS LTD. was served, via the Court's email notification system on the following counsel for Plaintiff on the 24th day of July 2007:

Lynn A. Malinoski
Woodcock Washburn, LLP
Cira Centre, 12th Floor
2929 Arch Street
Philadelphia, PA 19104-2891
Telephone: (215) 568-3100
Facsimile: (215) 568-3439

Daniel J. Gleason
Nutter McClennan & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210-2604
Telephone: (617) 439-2000
Facsimile: (617) 310-9000

/s/Charles W. Saber